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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,377	04/07/1999	ROBERT J. D'AMATO	05213-0272	6240

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/13/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/287,377

Applicant(s)

D'AMATO, ROBERT J.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-12, 15, 19-39 and 43-48 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 7-12, 15, 19-39 and 43-48 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 7-12, 15, 19-39 and 43-48 are pending.
2. Claims 7-12, 15, 19-39 and 43-48 are rejected.

### ***Rejection After Allowance***

3. Applicant is advised that the Notice of Allowance mailed October 11, 2002 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 15, 19, 20 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Billson et al. of WO 95/03807. Billson et al. teach of treating an inflammatory response in the macula of the eye, namely age-related macular

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degeneration, with the administration of anti-inflammatory steroids (see pages 2 and 3) along with an anti-angiogenesis agents, such as thalidomide, (see page 4, lines 1-4 and claims 1, 2, 5 and 11-13). Billson et al. teach the skilled artisan that other substances, such as anti-angiogenesis agents, can be added to the anti-inflammatory agent. Billson et al. state that amongst the various types of anti-inflammatory agents that may be utilized, a variety of anti-angiogenesis agents can be combined in a composition. As an illustration of an anti-angiogenesis agent, Billson et al. provide the example of thalidomide, (see page 4, lines 1-4 and claims 1, 2, 5 and 11-13). Furthermore, Billson et al. disclose that the steroid of triamcinolone acetonide is used to treat macular degeneration, (see page 4, lines 11-19).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)). (7-12-01)

8. Claims 15, 19, 20 and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Billson et al. of U.S. Patent No. 5,770,589. Billson et al. teach of a

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composition, which is comprised of an anti-inflammatory compound (see from column 1, line 60 to column 3, line 53) and an anti-angiogenesis inhibiting compound, which is comprised of thalidomide, (see column 3, lines 54-60 as well as claims 1, 3, 5 and 9-11) for the treatment of macular degeneration. Billson et al. teach the skilled artisan that other substances, such as anti-angiogenesis agents, can be added to the anti-inflammatory agent. Billson et al. state that amongst the various types of anti-inflammatory agents that may be utilized, a variety of anti-angiogenesis agents can be combined in a composition. As an illustration of an anti-angiogenesis agent, Billson et al. provide the example of thalidomide, (see page 4, lines 1-4 and claims 1, 2, 5 and 11-13). Furthermore, Billson et al. disclose that the steroid of triamcinolone acetonide is used to treat macular degeneration, (see column 3, lines 20-25, column 4, lines 1-4). (07-15-03)

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 7-12, 15, 19-39 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billson et al. of WO 95/03807. Billson et al. teach of treating an inflammatory response in the macula of the eye, namely age-related macular degeneration, with the administration of anti-inflammatory agent, (see abstract). Billson et al. teach that of an example of an anti-inflammatory agent that of steroids, (see pages 2 and 3). The skilled artisan would have been motivated from the teachings of Billson et al. to utilize other types of agents which possess the pharmacological property of inhibiting inflammation. Moreover, the prior art reference of Billson et al. disclose that the anti-inflammatory agents can be practiced alone or in conjunction with other therapies or agents, (see page 4, lines 1-4). Billson et al. teach the skilled artisan that other substances, such as anti-angiogenesis agents, can be added to the anti-inflammatory agent. Billson et al. state that amongst the various types of anti-inflammatory agents that may be utilized, a variety of anti-angiogenesis agents can be combined in a composition. As an illustration of an anti-angiogenesis agent, Billson et al. provide the example of thalidomide, (see page 4, lines 1-4 and claims 1, 2, 5 and 11-13). With this information provided from Billson et al., one having ordinary skill in the art is provided with the motivation to utilize any agent that is an angiogenesis agent, which would obviously embrace thalidomide as well as its derivatives and analogues. In addition, it is well established in the art that angiogenesis is the formation of new blood vessels into a tissue or organ. It is also well documented that unregulated angiogenesis

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occurs in numerous diseases states and conditions which are associated or dependent on angiogenesis, (for instance, see the instant section entitled Background of the Invention, pages 1-7 of this application). Accordingly, it would be obvious to the skilled artisan to treat these various disease states or conditions with angiogenesis inhibitors. Due to the fact that Billson et al. teach of the combined administration of an anti-inflammatory compound with an anti-angiogenesis agent, one having ordinary skill in the art would be motivated to treat a variety of conditions and ailments in which angiogenesis is unregulated. Furthermore, Billson et al. disclose that the steroid of triamcinolone acetonide is used to treat macular degeneration, (see page 4, lines 11-19). The determination of the mode, method and dosage of the administration of these pharmaceuticals is well within the purview of the skilled artisan. Clearly, one having ordinary skill in the art is provided with the motivation to utilize an anti-inflammatory agent along with that of anti-angiogenesis agent from the teachings and support from Billson et al. In addition, the skilled artisan would have been motivated to utilize and substitute other agents, as well as their respective derivatives and analogues, to just as long as they maintain the pharmaceutical properties of being known as anti-inflammatory agents as well as anti-angiogenesis agents. For these reasons, the instant invention is rendered obvious over the prior art reference of Billson et al.

12. Claims 7-12, 15, 19-39 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billson et al. of WO 95/03807 in view of Little, II et al of U.S. Patent No. 5,348,942. Billson et al. teach of treating an inflammatory response in the macula of the eye, namely age-related macular degeneration, with the administration of anti-

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inflammatory agent, (see abstract). Billson et al. teach that of an example of an anti-inflammatory agent that of steroids, (see pages 2 and 3). The skilled artisan would have been motivated from the teachings of Billson et al. to utilize other types of agents which possess the pharmacological property of inhibiting inflammation. Moreover, the prior art reference of Billson et al. disclose that the anti-inflammatory agents can be practiced alone or in conjunction with other therapies or agents, (see page 4, lines 1-4). Billson et al. teach the skilled artisan that other substances, such as anti-angiogenesis agents, can be added to the anti-inflammatory agent. Billson et al. state that amongst the various types of anti-inflammatory agents that may be utilized, a variety of anti-angiogenesis agents can be combined in a composition. As an illustration of an anti-angiogenesis agent, Billson et al. provide the example of thalidomide, (see page 4, lines 1-4 and claims 1, 2, 5 and 11-13). With this information provided from Billson et al., one having ordinary skill in the art is provided with the motivation to utilize any agent that is an angiogenesis agent, which would obviously embrace thalidomide as well as its derivatives and analogues. In addition, it is well established in the art that angiogenesis closely associated with endothelial cell proliferation and constitutes the development of new capillary blood vessels.

13. Angiogenesis is also associated with a variety of pathological conditions in which it would be desirable to inhibit such new blood vessel development, inter alia, the growth of tumors, diabetic retinopathy, retrolental fibroplasias, neovascular glaucoma, psoriasis, rheumatoid arthritis, hemangiomas, Kaposi's sarcoma, (see column 2, lines 14-38 of Little, II et al.). Accordingly, it would be obvious to the skilled artisan to treat these



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various disease states or conditions with angiogenesis inhibitors, as suggested by Billson et al. and Little, II et al. Due to the fact that Billson et al. teach of the combined administration of an anti-inflammatory compound with an anti-angiogenesis agent, one having ordinary skill in the art would be motivated to treat a variety of conditions and ailments in which angiogenesis is unregulated. Furthermore, Billson et al. disclose that the steroid of triamcinolone acetonide is used to treat macular degeneration, (see page 4, lines 11-19). The determination of the mode, method and dosage of the administration of these pharmaceuticals is well within the purview of the skilled artisan. Clearly, one having ordinary skill in the art is provided with the motivation to utilize an anti-inflammatory agent along with an anti-angiogenesis agent from the teachings and support from Billson et al. and Little, II et al. In addition, the skilled artisan would have been motivated to utilize and substitute other agents, as well as their respective derivatives and analogues, to just as long as they maintain the pharmaceutical properties of being known as anti-inflammatory agents as well as anti-angiogenesis agents. For these reasons, the instant invention is rendered obvious over the prior art reference of Billson et al. and Little, II et al.

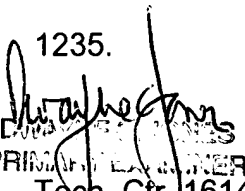
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
EXAMINER  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
February 6, 2003